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Description

Field of the Invention

This invention relates to stents and a method of making a stent.

Description of the Prior Art :

It is desirable in various situations to provide means for expanding a constricted vessel or for maintaining an open passageway through a vessel. Such situations arise, for instance, after an angioplasty of a coronary artery. In these situations, wire stents, are useful to prevent restenosis of the dilated vessel, or to eliminate the danger of occlusion caused by "flaps" resulting from intimal tears associated with angioplasty. Wire stents can also be used to reinforce collapsing structures in the respiratory and biliary tracts.

Typical of the wire stents of the prior art is the stent of Gianturco, U.S. Patent No. 4,580,568, wherein the stent is compressed and encased in a sheath. The sheath is then positioned in the vascular system and the stent is held in position by a flat-ended pusher while the sheath is withdrawn. The zig-zag configuration of this particular stent allows it to expand in the passageway to hold the passageway open and enlarged.

Stents comprised of variously shaped spiral springs are described by Maass et al. in U.S. Patent No. 4,553,545, and in Radiology Follow-Up of Transluminally Inserted Vascular Endoprosthesis : An Experimental Study Using Expanding Spirals, Radiology, September 1984 ; 152 : 659-663. Applications of torque to the end of these spiral springs increases the number of coils while decreasing the stent diameter for insertion. Once inserted, an opposite torque is applied to the spiral springs causing the stent diameter to increase. Use of this type of stent requires a sophisticated coaxial cable to apply torque to the stent once it has been inserted into the vessel.

Dotter et al. reported the use of a prosthesis constructed of a thermal shape memory alloy which is passed into the passageway through a catheter. See, Dotter CT et al., Transluminal Expandable Nitinol Coil Stent Grafting : Preliminary Report, Radiology, April, 1983 ; 147 : 259-260. This coil stent is compacted by cooling, inserted, and then heated in situ until the stent expands in the passageway. This stent is positioned within the vessel by a detachable positioning device capable of supplying electrical energy to heat the thermal coil.

Other references which may have relevance to the present invention are the following U.S. patents : Abolins, No. 3,278,176 ; Alfidi et al., No. 3,868,956 ; Simon, No. 4,425,908 ; and Sakura, Jr., 4,214,587.

Among the drawbacks of the prior art wire stents and expandable coil stents are that these stents are either difficult to produce or complicated to insert into a body passageway. Each of these stents requires the use of a complex device for insertion and expansion of the stent within the vessel. On the other hand, less complex wire stents lack the axial compliance to pass through a catheter that has any significant curves or bends. The present invention addresses each of these problems by providing a wire stent that is easy to produce, simple to install and capable of delivery around curves and bends in a vessel or passageway.

Summary of the Invention

A stent comprising a wire formed into a serpentine configuration including a series of straight sections and a plurality of bends. The straight sections are joined by the bends to form a series of alternating loops. The serpentine configuration is formed into a cylindrical shape having a longitudinal axis, wherein the straight sections are bent into generally circular configurations surrounding and generally perpendicular to the longitudinal axis. Means are provided for expanding the circular configurations and, consequently, the cylindrical shape, comprising a balloon catheter. The balloon catheter is folded and received within the cylindrical shape and extends along the axis of the cylindrical shape. The straight sections are formed about the balloon catheter such that adjacent loops diverge circumferentially relative to each other as the balloon is inflated.

Brief Description of the Drawings

FIG. 1 is a perspective view of a wire stent of the present invention.

FIG. 2 is an end view of the wire stent of FIG. 1.

FIG. 3 is a side view of the wire stent of FIG. 1 engaged around a folded balloon catheter and shown in the contracted condition.

FIG. 4 is a side view of the wire stent and balloon catheter of FIG. 3, shown in the expanded condition.

FIG. 5 is a fragmentary exploded view of a portion of a wire stent of FIG. 1.

FIG. 6 is a cutaway view of a body cavity with the wire stent and balloon catheter situated in a curve in the cavity.

FIG. 7 is the cutaway view similar to FIG. 6 with the stent and balloon catheter situated within the cavity adjacent an occlusion in the cavity.

FIG. 8 is the cutaway view of FIG. 7, shown with the balloon catheter inflated and with the stent in contact with the cavity wall to remove the occlusion.

FIG. 9 is a perspective view of a step of a method of the present invention showing a wire formed into a planar serpentine configuration and placed on a forming die.

FIG. 10 is a cross-sectional view of the forming die in FIG. 9 taken along line 10-10 and viewed in the direction of the arrows.

FIG. 11 is a perspective view of the wire pressed into a trough in the forming die by a forming bar.

FIG. 12 is a cross-sectional view of the forming die and forming bar of FIG. 11 taken along line 12-12 and viewed in the direction of the arrows.

FIG. 13 is a perspective view similar to FIG. 11 and showing the loops of the serpentine configuration pulled over the exposed portion of the forming bar by pulling tools.

FIG. 14 is a cross-sectional view of the forming die and forming bar in FIG. 13 taken along line 14-14 and viewed in the direction of the arrows.

FIG. 15 is a perspective of a balloon catheter inserted through a generally cylindrical opening formed by the wire in one step of the present method.

Description of the Preferred Embodiment

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring to FIG. 1, a wire stent 10 is shown as having a longitudinal axis 26. The stent comprises a plurality of curved sections 11 that are situated generally perpendicular to the axis 26. Adjacent curved sections 11 are joined by bends or cusps 13. A loop 18 is formed at each free end of the wire stent 10 in order to shield the wire end. The curved sections 11 are formed into a circular configuration, as shown in the end view of FIG. 2, so that the stent 10 has a cylindrical opening 12 formed therein.

The curved sections 11 and cusps 13 form a series of alternating clockwise and counter-clockwise loops 15 and 16, respectively. The clockwise direction relative to the axis 26 has been arbitrarily selected and is noted by the heavy arrow 27 in FIG. 1. In the contracted condition of the stent 10, these loops 15 and 16 overlap longitudinally, as demonstrated by the overlap region 20 shown in FIG. 3. Thus, the overlap region 20 gives the appearance that the stent is a continuous circular ring when viewed from an end, although when viewed as in FIGS. 1 or 3 it is apparent that the cylindrical shape of the stent 10 is discontinuous. The importance of this feature is illustrated by a comparison of FIGS. 3 and 4.

In FIG. 3, the stent 10 is shown secured around a catheter 22, which has an inflatable balloon 23 adhered thereon surrounding a feed orifice 22a in the catheter. The balloon used in this embodiment is a folded balloon in which flaps 23a of the balloon 23 are folded over the catheter 22, as shown in FIG. 3. The folded flaps 23a allow the balloon 23 to inflate to a specific diameter without excessively stretching the balloon material and risking a rupture of the balloon.

The stent is compressed about the catheter 22 and balloon 23 so that it assumes a contracted outer diameter 24, which is calibrated to allow insertion into a particular body passageway. The clockwise loops 15 and counter-clockwise loops 16 overlap in the region 20, and the spring stiffness of the wire keeps the stent in this position during insertion. The stent 10 remains in tight contact with the catheter 22 even as the assembly is delivered around curves and bends in a body passageway.

After the catheter and stent are fully inserted into the passageway, the balloon 23 is inflated to a diameter 25, which is calibrated to force the stent 10 into contact with the passageway inner surface and, at least in some cases, to expand the passageway. As the balloon is inflated, the clockwise and counter-clockwise loops 15 and 16 diverge circumferentially until the longitudinal overlap between loops is reduced to the region 21, shown in FIG. 4. Thus, the effective diameter of the stent 10 relative to the longitudinal axis 26 is increased without thermal expansion or application of torsional forces to the stent, as suggested in the prior art.

In the best mode of the invention, the wire comprising the stent 10 is made of a malleable material, preferably from the group comprising annealed stainless steel, tungsten and platinum. This malleable material is sufficiently deformable to allow the loops 15 and 16 to diverge due to radially outward pressure applied by inflation of the membrane that comprises the standard balloon catheter. Because the stent material is plastic, rather than elastic, the stent retains the enlarged diameter after the balloon 23 is deflated and the catheter 22 removed. However, the material has sufficient strength and stiffness to avoid the stent being displaced on the balloon during insertion and to avoid the loops 15 and 16 being forced into an overlying relation. Further, the stent has sufficient strength and stiffness to allow it to maintain its position in the passageway and to resist being dislodged after the catheter 22 has been removed and the balloon is no longer stabilizing the stent. One example of a suitable wire has an outer diameter of 0.0018 inches and is stainless steel AISI 316 alloy.

It is desirable that the overlap region 20 in the contracted condition be sufficiently large so that the stent has a high contact area with the catheter, providing additional protection against the stent becoming dislodged while the assembly is inserted. In the expanded condition, the overlap region 21 should be

sufficiently large to provide continuous circumferential support for the passageway in which the stent is inserted. In one example of the invention, the overlaying region 20 extends almost 360° circumferentially. For clarity, the illustrated embodiment shows the overlap 20 to be substantially less.

It can be observed that applicant's preferred embodiment can be dissected into single coil helical sections. FIG. 5 is an exploded view of a wire stent 49 having a longitudinal axis 50. The clockwise direction, according to a right-hand rule, is denoted by the heavy arrow 48 about the axis 50. The stent 49 comprises a series of alternating single coil clockwise helical sections 51 and single coil counter-clockwise helical sections 52. The helical sections 51 and 52 have forward ends 51a and 52a, and aft ends 51b and 52b, respectively. The adjacent helical sections are joined by cusps 53, with the forward end of one helical section being connected to the aft end of the next helical section. Thus, end 51a of the clockwise helical section 51 is joined to end 52b of the counter-clockwise helical section 52, while end 52a is connected to end 51b.

In a method of using the stent of the present invention, a stent and balloon catheter assembly 80 is inserted into a passageway 72, such as an artery, in a patient's body 70, as shown in FIG. 6. The assembly 80 is in the deflated configuration as it is maneuvered around the curve 76 in the passageway 72. The stiffness of the catheter 82 allows the assembly 80 to follow the curve 76, while the strength and stiffness of the stent 84 keeps it tightly engaged on the catheter balloon 86 during insertion. The passageway has an occlusion 74 situated at another bend in the passageway.

In FIG. 7, the stent and balloon catheter assembly 80 is shown fully inserted into the passageway 72 so that the stent 84 and balloon 86 are situated directly adjacent the occlusion 74 and following the curve of the passageway. The assembly is shown in the expanded configuration 80' in FIG. 8, in which the balloon 86' is inflated and the wire stent 84' expanded to contact and enlarge the passageway 72. The expansion is exaggerated in FIG. 8 for clarity. The assembly is expanded a sufficient amount to remove the occlusion 74 (FIG. 7) and open the passageway. The balloon is then deflated and the catheter removed, leaving the stent to hold the passageway open.

The method of the present invention concerns a process for fabricating a stent. Referring to FIG. 9, a wire 30 is bent into a planar serpentine shape. The shape includes a series of straight sections 33 joined by bends or cusps 35. After the forming procedure has occurred, the straight sections 33 become curved sections 11, and cusps 35 become cusps 13. Also, the portions of wire 30 on either side of the centerline 31 become the clockwise and counter-clockwise loops 15 and 16, as designated in FIG. 9. Free end 60 can be formed into a loop, such as loop 18 in FIG. 1.

A forming die 39 comprises a flat plate 40 having a straight trough 42 formed therein. In the cross-sectional view of FIG. 10, it is seen that the trough 42 has a semi-circular surface 43. The wire 30 is placed flat upon the plate such that the centerline 31 is coincident with the centerline of the trough 42.

The wire 30 is pressed into the trough 42 and against the semi-circular surface 43 using a forming bar 45, as shown in FIGS. 11 and 12. The forming bar 45 is held in place by elastic bands 46. The ends of the loops 15 and 16 project upwardly or outwardly from the trough 42 and above the surface of the flat plate 40. In the next step of the present method, pulling tools 47 are used to pull the loops 15 and 16 over the exposed surface 45a (FIG. 12) of the forming bar 45, as shown in FIGS. 13 and 14. Hooks 47a at the end of pulling tools 47 engage the cusps 13 of the loops 15 and 16 during this pulling step. Next, the partially formed stent is removed from the plate 40 by lifting the forming bar away from the plate. The bar 45 is removed, leaving the configuration of the partially formed stent at this point is as shown in FIG. 15.

The balloon catheter 22 is inserted through the longitudinal cylindrical opening 12 in the stent 10, as shown in FIG. 15, and the ends of the loops 15 and 16 are pressed into contact with the catheter, as shown in FIG. 3. As mentioned, when the loops 15 and 16 are in their final overlapping position, it is preferred that they overlap a substantial amount. In one example of the invention, this overlap 20 (FIG. 3) is about 360 degrees. The balloon catheter used could be of various designs, such as the design shown in the patent to William A. Cook, U.S. No. 4,637,396, or as available from Cook, Inc. of Bloomington, Indiana, under their catalogue number OMG 4.0-4.5 and 5.3 FR catheter.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative in character, it being understood that only the preferred embodiment has been shown and described.

Claims

1. A stent comprising a wire formed into a serpentine configuration including a series of straight sections (33) and a plurality of bends (35), said straight sections being joined by said bends to form a series of alternating loops (15) and (16), said serpentine configuration being formed into a cylindrical shape having a longitudinal axis (31) and wherein said straight sections are bent into generally circular configurations surrounding and generally perpendicular to said axis, and means for expanding said circular configurations.

2. The stent of Claim 1, wherein said wire is made of malleable material.

3. The stent of Claim 1, wherein said wire is made of malleable material from the group consisting of annealed stainless steel, tungsten and platinum.

4. The stent of Claim 1, wherein said means for expanding is a balloon catheter (22), said balloon catheter being received within said cylindrical shape and extending along said axis.

5. The stent of Claim 4, wherein said balloon catheter is a folded balloon catheter.

6. The stent of Claim 1, wherein said circular configurations have a contracted condition in which said alternating loops include longitudinally overlapping portions (20) adjacent said bends.

7. The stent of Claim 6, wherein said circular configurations further have an expanded condition in which said longitudinally overlapping portions (20) of adjacent loops are circumferentially diverged relative to said contracted condition.

8. The stent of Claim 7, wherein said means for expanding is a balloon catheter (22), and said balloon catheter is folded and received within said cylindrical shape and extends along said axis.

9. The stent of Claim 1, wherein said alternating loops include longitudinally overlapping portions adjacent said bends which are arranged to diverge circumferentially in response to expansion of said means for expanding.

10. The stent of Claim 9, wherein said means for expanding is a balloon catheter, and said balloon catheter is folded and received within said cylindrical shape and extends along said axis.

11. The stent of Claim 1, wherein said wire includes two opposite ends, said wire being formed into a loop (18) adjacent each of said ends such that said ends are substantially shielded.

12. The stent of Claim 1, wherein said wire has a outer diameter of 0.0018 inches.

13. A stent having a longitudinal axis and comprising : a plurality of longitudinally-spaced wire loops, each having a cusp, adjacent ones of said loops sharing a common length of wire, each of said loops being formed about said longitudinal axis into a discontinuous cylindrical shape such that said cylindrical shape can be expanded or contracted by displacing said loops circumferentially ; and means for expanding said cylindrical shape from a contracted condition to an expanded condition.

14. A stent according to Claim 13, wherein said loops are arranged so that said cusps of adjacent loops are in opposing orientation.

15. A stent according to Claim 13, wherein : said loops are arranged so that said cusps of adjacent loops are in opposing orientation ; and said contracted condition includes said cylindrical shape having a first overlap region (20) in which adjacent ones of said loops longitudinally overlap each other.

16. A stent according to Claim 15, wherein said expanded condition includes said cylindrical shape having a second overlap region (21) in which adjacent ones of said loops longitudinally overlap each other, said second overlap region being smaller than said first overlap region.

17. A stent according to Claim 13, wherein said means for expanding includes a balloon catheter extending along said longitudinal axis and received through said cylindrical shape.

18. A stent according to Claim 17, wherein said means for expanding includes a folded balloon catheter.

19. The stent according to Claim 13, wherein each of said wire loops is made of malleable material.

20. The stent of Claim 13, wherein each of said wire loops has a wire outer diameter of 0.0018 inches.

21. A wire stent (49) having a longitudinal axis and comprising :

alternating clockwise and counterclockwise single coil helical sections (51) and (52) situated about said longitudinal axis, adjacent ones of said helical sections being joined at a cusp (53) ; and means for expanding said helical sections from a contracted condition to an expanded condition such that adjacent cusps are displaced circumferentially relative to each other.

22. A stent according to Claim 21, wherein said means for expanding is a folded balloon catheter extending along said longitudinal axis and received through each of said helical sections.

23. The stent according to Claim 21, wherein said helical sections are made of malleable material.

24. The stent of Claim 21, wherein each of said helical sections has a wire outer diameter of 0.0018 inches.

25. A method for making the stent according to Claims 1 to 24 comprising the steps of :

(a) forming a wire into a planar serpentine configuration having a series of alternating opposing loops, each with a closed end ;

(b) placing said wire on a flat surface (40) having a trough (42) with a semi-cylindrical wall (43), said wire being situated over said trough such that said serpentine configuration is generally centred over said trough ;

(c) using a cylindrical tool (45), forcing said wire into said trough between said cylindrical tool and said semi-circular wall ; and

(d) forcing said opposing loops (15) and (16) over said cylindrical tool to form said wire into a generally cylindrical shape having a longitudinal axis, such that said loops lie longitudinally adjacent each other.

26. The method of Claim 25, further comprising the steps of :

(e) removing said cylindrical tool (45) and removing said wire from said trough (42) ;

(f) inserting a folded balloon catheter (22) into said cylindrical shape ; and

(g) tightening said cylindrical shape about said balloon catheter such that the wire contacts the balloon catheter along its entire length and adjacent loops have longitudinally overlapping portions (20) adjacent the closed ends of said loops.

27. The method of Claim 25, wherein the step of forming a wire into a planar serpentine configuration includes the step of forming a loop (18) adjacent each of the free ends of the wire.

Patentansprüche

1. Dilatator mit einem Draht, der in eine schlangenförmige Konfiguration geformt ist, die eine Reihe gerader Abschnitte (33) und eine Vielzahl Biegungen (35) aufweist, wobei die geraden Abschnitte durch die Biegungen verbunden sind, um eine Reihe alternierender Schlaufen (15, 16) auszubilden, wobei die schlangenförmige Konfiguration in eine zylindrische Form mit einer Längsachse (31) geformt ist und wobei die geraden Abschnitte in etwa kreisförmige Konfigurationen gebogen sind, die die Achse umgeben und etwa lotrecht zu ihr angeordnet sind, und mit einer Vorrichtung zur Ausweitung der kreisförmigen Konfigurationen.

2. Dilatator nach Anspruch 1, bei dem der Draht aus einem verformbaren Werkstoff hergestellt ist.

3. Dilatator nach Anspruch 1, bei dem der Draht aus einem verformbaren Werkstoff aus der vergüteten rostfreien Stahl, Wolfram und Platin enthaltenden Gruppe hergestellt ist.

4. Dilatator nach Anspruch 1, bei dem die Vorrichtung zur Erweiterung ein Ballonkatheter (22) ist, der innerhalb der zylindrischen Form aufgenommen ist und sich längs der Achse erstreckt.

5. Dilatator nach Anspruch 4, bei dem der Ballonkatheter ein gefalteter Ballonkatheter ist.

6. Dilatator nach Anspruch 1, bei dem die kreisförmigen Konfigurationen einen zusammengezogenen Zustand haben, in dem die alternierenden Schlaufen einander in Lägsrichtung überlappende Abschnitte (20) neben den Biegungen einschliessen.

7. Dilatator nach Anspruch 6, bei dem die kreisförmigen Konfigurationenn des weiteren einen ausgeweiteten Zustand aufweisen, in dem die einander in Längsrichtung überlappenden Abschnitte (20) benachbarter Schlaufen in Umfangsrichtung in bezug auf den zusammengezogenen Zustand abweichen.

8. Dilatator nach Anspruch 7, bei dem die Vorrichtung zur Erweiterung ein Ballonkatheter (22) ist, der gefaltet und innerhalb der zylindrischen Form aufgenommen ist und der sich längs der Achse erstreckt.

9. Dilatator nach Anspruch 1, bei dem die alternierenden Schlaufen in Längsrichtung einander überlappende Abschnitte neben den Biegungen aufweisen, die so angeordnet sind, daß sie in Umfangsrichtung entsprechend der Erweiterung der Vorrichtung zur Erweiterung abweichen.

10. Dilatator nach Anspruch 9, bei dem die Vorrichtung zur Erweiterung ein Ballonkatheter ist, der gefaltet und innerhalb der zylindrischen Form aufgenommen ist und sich längs der Achse erstreckt.

11. Dilatator nach Anspruch 1, bei dem der Draht zwei entgegengesetzte Enden aufweist, wobei der Draht in eine Schlaufe (18) neben jedem dar beiden Enden geformt ist, so daß die Enden etwa abgeschirmt sind.

12. Dilatator nach Anspruch 1, bei dem der Draht einen Außendurchmesser von 0.0018 Inches aufweist.

13. Dilatator mit einer Längsachse und einer Vielzahl in Längsrichtung beabstandeter Drahtschlaufen, von denen jede einen Scheitelpunkt aufweist, wobei einander benachbarte Schlaufen ein ihnen gemeinsames Drahtlängenstück teilen und wobei jede Schlaufe so um die Längsachse in eine diskontinuierliche zylindrische Form geformt ist, daß die zylindrische Form durch Versetzung der Schlaufen in Umfangsrichtung ausgeweitet oder zusammengezogen werden kann, und mit einer Vorrichtung zur Erweiterung der zylindrischen Form aus einem zusammengezogenen in einen ausgeweiteten Zustand.

14. Dilatator nach Anspruch 13, bei den die Schlaufen so angeordnet sind, daß die Scheitelpunkte einander benachbarter Schlaufen einander gegenüber angeordnet sind.

15. Dilatator nach Anspruch 13, bei dem die Schlaufen so angeordnet sind, daß die Scheitelpunkte einander benachbarter Schlaufen in Gegenüberlage orientiert sind, und der zusammengezogene Zustand die zylindrische Form umfaßt, die einen ersten Überlappungsbereich (20) aufweist, in dem einander benachbarte Schlaufen einander in Längsrichtung überlappen.

16. Dilatator nach Anspruch 15, bei dem der erweiterte Zustand die zylindrische Form aufweist, die einen zweiten Überlappungsbereich (21) hat, in dem einander benachbarte Schlaufen einander in Längsrichtung überlappen, wobei der zweite Überlappungsbereich kleiner als der erste Überlappungsbeteich ist.

17. Dilatator nach Anspruch 13, bei dem die Vorrichtung zur Erweiterung einen Ballonkatheter aufweist, der sich längs der Längsachse erstreckt und der in der zylindrischen Form aufgenommen ist.

18. Dilatator nach Anspruch 17, bei dem die Vorrichtung zur Erweiterung einen gefalteten Ballonkatheter aufweist.

19. Dilatator nach Anspruch 13, bei dem jede Drahtschlaufe aus einem verformbaren Werkstoff hergestellt ist.

20. Dilatator nach Anspruch 13, bei dem jede Drahtschlaufe einen Drahtaußendurchmesser von 0,0018 Inches hat.

21. Drahdilatator (49) mit einer Längsachse und

alternierenden in Uhrzeiger- und in Gegenuhrzeigerrichtung gebogenen einzelnen Spiralfederabschnitten (51, 52), die um die Längsachse gelegen sind, wobei einander benachbarte Spiralabschnitte an einem Scheitelpunkt (53) miteinander verbunden sind, und einer Vorrichtung zur Erweiterung der Spiralabschnitte aus einem zusammengezogenen Zustand in einen aufgeweiteten Zustand, so daß einander benachbarte Scheitelpunkte in Umfangsrichtung zueinander versetzt sind.

22. Dilatator nach Anspruch 21, bei dem die Einrichtung zur Erweiterung ein gefalteter Ballonkatheter ist, der sich längs der Längsachse erstreckt und der durch jeden der Spiralabschnitte aufgenommen ist.

23. Dilatator nach Anspruch 21, bei dem die Spiralabschnitte aus einem verformbaren Werkstoff hergestellt sind.

24. Dilatator nach Anspruch 21, bei dem jeder Spiralabschnitt einen Drahtaußendurchmesser von 0,0018 Inches hat.

25. Verfahren zur Herstellung des Dilatators nach den Ansprüchen 1-24 mit den folgenden Verfahrensschritten :

(a) Formung eines Drahts in eine planare schlangenförmige Konfiguration mit einer Reihe alternierender gegenüberliegender Schleifen, jeweils mit einem geschlossenen Ende ;

(b) Anordnen des Drahts auf einer flachen Oberfläche (40) mit einer Rinne (42) mit einer halbzylindrischen Wand (43), wobei der Draht über der Rinne angeordnet wird, so daß die schlangenförmige Konfiguration etwa mittig über der Rinne angeordnet ist ;

(c) Gebrauch eines zylindrischen Werkzeugs (45), Drücken des Drahts in die Rinne zwischen dem zylindrischen Werkzeug und der halbzylindrischen Wand ; und

(d) Drücken der einander gegenüberliegenden Schlaufen (15, 16) über das zylindrische Werkzeug, um den Draht in eine etwa zylindrische Form mit einer Längsachse zu formen, so daß die Schlaufen in Längsrichtung nebeneinander angeordnet sind.

26. Verfahren nach Anspruch 15, das weiterhin die Verfahrensschritte aufweist :

(e) Zurückziehen des zylindrischen Werkzeugs (45) und Zurückziehen des Drahts von der Rinne (42) ;

(f) Einsetzen eines gefalteten Ballonkatheters (22) in die zylindrische Form ; und

(g) Befestigen der zylindrischen Form um den Ballonkatheter, so daß der Draht den Ballonkatheter entlang dessen gesamter Länge kontaktiert und einander benachbarte Schlaufen in Längsrichtung überlappende Abschnitte (20) neben den geschlossenen Enden der Schlaufen aufweisen.

27. Verfahren nach Anspruch 25, bei dem der Verfahrensschritt des Formens eines Drahts in eine planare schlangenförmige Konfiguration den Verfahrensschritt einer Formung einer Schlaufe (18) neben jedem der freien Enden des Drahts aufweist.

Revendications

1. Un dilatateur comprenant un fil ayant une configuration en serpentin comprenant une série de parties rectilignes (33) et une pluralité de parties incurvées (35), lesdites parties rectilignes étant réunies par lesdites parties incurvées afin de former une série alternée de boucles (15) et (16), ladite configuration en serpentin étant mise en forme de cylindre ayant un axe longitudinal (31) et dans lequel lesdites parties rectilignes sont pliées afin d'avoir des configurations sensiblement circulaires entourant ledit axe et sensiblement perpendiculaires audit axe, et un moyen de dilatation de ladite configuration circulaire.

2. Le dilatateur selon la revendication 1, caractérisé en ce que ledit fil est réalisé à partir d'un matériau malléable.

3. Le dilatateur selon la revendication 1, caractérisé en ce que ledit fil est réalisé à partir d'un matériau malléable choisi dans le groupe comprenant l'acier inoxydable, le tungstène et le platine recuits.

4. Le dilatateur selon la revendication 1, caractérisé en ce que ledit moyen de dilatation desdites configurations circulaires est un cathéter gonflable (22), ledit cathéter gonflable étant reçu à l'intérieur de ladite forme cylindrique et s'étendant le long dudit axe.

5. Le dilatateur selon la revendication 4, caractérisé en ce que ledit cathéter gonflable est un cathéter comprenant un ballon plié.

6. Le dilatateur selon la revendication 1, caractérisé en ce que lesdites configurations circulaires possèdent une position contractée dans laquelle lesdites boucles alternées comportent des parties (20) adjacentes auxdites parties incurvées de recouvrement longitudinal.

7. Le dilatateur selon la revendication 6, caractérisé en ce que lesdites configurations circulaires possèdent une position dilatée dans laquelle lesdites parties (20) de recouvrement longitudinal des boucles adjacentes divergent circonférentiellement par rapport à ladite position contractée.

8. Le dilatateur selon la revendication 7, caractérisé en ce que ledit moyen d'expansion de la forme circulaire est un cathéter gonflable (22) et en ce que ledit cathéter gonflable est plié et reçu à l'intérieur de ladite forme cylindrique et s'étend le long de son axe.

9. Le dilatateur selon la revendication 1, caractérisé en ce que lesdites boucles alternées comportent des parties qui se chevauchent longitudinalement et sont adjacentes auxdites parties incurvées et qui sont disposées pour diverger circonférentiellement suite à

l'expansion dudit moyen d'expansion.

10. Le dilatateur selon la revendication 9, caractérisé en ce que ledit moyen d'expansion de la forme circulaire est un cathéter gonflable et en ce que ledit cathéter gonflable est plié et reçu à l'intérieur de ladite forme cylindrique et s'étend le long de son axe.

11. Le dilatateur selon la revendication 1, caractérisé en ce que ledit fil comporte deux extrémités opposées, ledit fil étant plié en forme de boucle (18) à chacune de ses extrémités de sorte que lesdites extrémités sont substantiellement protégées.

12. Le dilatateur selon la revendication 1, caractérisé en ce que ledit fil a un diamètre extérieur de 0,046 mm (0,0018 inches).

13. Un dilatateur ayant un axe longitudinal et comprenant : une pluralité de boucles réalisées dans un fil espacées longitudinalement, chaque boucle ayant un lobe, les boucles adjacentes auxdits lobes partageant une longueur de fil commune, chacune desdites boucles étant formée autour dudit axe longitudinal pour réaliser une forme cylindrique discontinue telle que ladite forme cylindrique puisse être expansée ou contractée en déplaçant lesdites boucles circonférentiellement ; et un moyen d'expansion de ladite forme cylindrique d'une position contractée à une position expansée.

14. Un dilatateur selon la revendication 13, caractérisé en ce que lesdites boucles sont disposées afin que lesdits lobes des boucles adjacentes ont une orientation opposée.

15. Un dilatateur selon la revendication 13, caractérisé en ce que lesdites boucles sont disposées de manière à ce que lesdits lobes des boucles adjacentes ont une orientation opposée et ladite position contractée correspond à l'existence d'une première zone de recouvrement (20) dans ladite forme cylindrique, les boucles adjacentes se recouvrant mutuellement longitudinalement à l'intérieur de cette zone.

16. Un dilatateur selon la revendication 15, caractérisé en ce que, dans ladite position expansée, ladite forme cylindrique possède une deuxième zone de recouvrement (21) dans laquelle les boucles adjacentes se recouvrent mutuellement longitudinalement, ladite deuxième zone de recouvrement étant plus petite que ladite première zone de recouvrement.

17. Un dilatateur selon la revendication 13, caractérisé en ce que ledit moyen d'expansion comporte un cathéter gonflable qui s'étend le long dudit axe longitudinal et qui est reçu à l'intérieur de ladite forme cylindrique.

18. Un dilatateur selon la revendication 17, caractérisé en ce que ledit moyen d'expansion comporte un cathéter contenant un ballon plié.

19. Le dilatateur selon la revendication 13, caractérisé en ce que chacune desdites boucles de fil est réalisée dans un matériau malléable.

20. Le dilatateur selon la revendication 13, caractérisé en ce que le fil de chacune desdites boucles a un diamètre extérieur du fil de 0,046 mm (0,0018 inches).

21. Un dilatateur (49) réalisé en fil et ayant un axe longitudinal et comprenant :

— des parties hélicoïdales (51 et 52) d'une seule spire disposées alternativement selon le sens des aiguilles d'une montre et selon le sens inverse des aiguilles d'une montre, situées autour dudit axe longitudinal, lesdites parties hélicoïdales adjacentes étant réunies par un lobe (53) ; et

— un moyen d'expansion desdites parties hélicoïdales à partir d'une position contractée à une position expansée de manière à ce que les lobes adjacents se déplacent circonférentiellement l'un par rapport à l'autre.

22. Le dilatateur selon la revendication 21, caractérisé en ce que ledit moyen d'expansion est un cathéter gonflable comprenant un ballon plié qui s'étend le long dudit axe longitudinal et qui est reçu à l'intérieur de chacune desdites parties hélicoïdales.

23. Le dilatateur selon la revendication 21, caractérisé en ce que lesdites parties hélicoïdales sont réalisées dans un matériau malléable.

24. Le dilatateur selon la revendication 21, caractérisé en ce que chacune desdites parties hélicoïdales est réalisée dans un fil ayant un diamètre extérieur de 0,046 mm (0,0018 inches).

25. Un procédé pour réaliser le dilatateur selon les revendications 1 à 24, comprenant les étapes de:

(a) la configuration d'un fil en forme de serpentin plan ayant une série de boucles disposées alternativement en opposition, chacune ayant une extrémité fermée ;

(b) la mise en place dudit fil sur une surface plane (40) ayant une rainure (42) comprenant une paroi semi-cylindrique (43), ledit fil étant situé au-dessus de ladite rainure de manière à ce que ladite configuration en serpentin se trouve sensiblement centrée au-dessus de ladite rainure ;

(c) le forçage, au moyen d'un outil cylindrique (45) dudit fil à l'intérieur de ladite rainure entre ledit outil cylindrique et ladite paroi semi-circulaire ; et

(d) le forçage desdites boucles (15) et (16) par-dessus ledit outil cylindrique pour former ledit fil en une configuration généralement cylindrique ayant un axe longitudinal de manière à ce que lesdites boucles se trouvent adjacentes l'une à l'autre dans le sens longitudinal.

26. Le procédé selon la revendication 25, caractérisé en ce qu'il comprend les étapes supplémentaires consistant à :

(e) enlever ledit outil cylindrique (45) et enlever ledit fil de ladite rainure (42) ;

(f) l'insertion d'un cathéter gonflable contenant un ballon plié (22) à l'intérieur de ladite configuration cylindrique ; et

(g) le serrage de ladite configuration cylindrique autour dudit cathéter gonflable de façon à ce que

le fil vienne en contact avec le cathéter gonflable sur toute sa longueur et que des boucles adjacentes aient des parties (20) de recouvrement longitudinal, adjacentes aux extrémités fermées desdites boucles.

27. Le procédé selon la revendication 25, caractérisé en ce que l'étape de configuration d'un fil en forme de serpentin plan comporte l'étape de la formation d'une boucle (18) adjacente à chaque extrémité libre du fil.

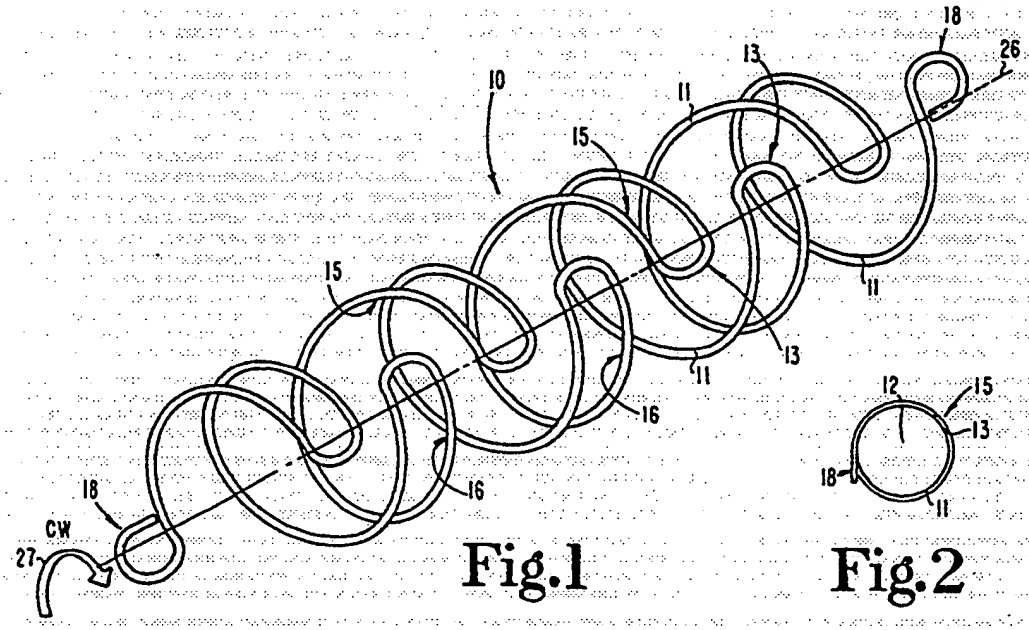


Fig.1

Fig.2

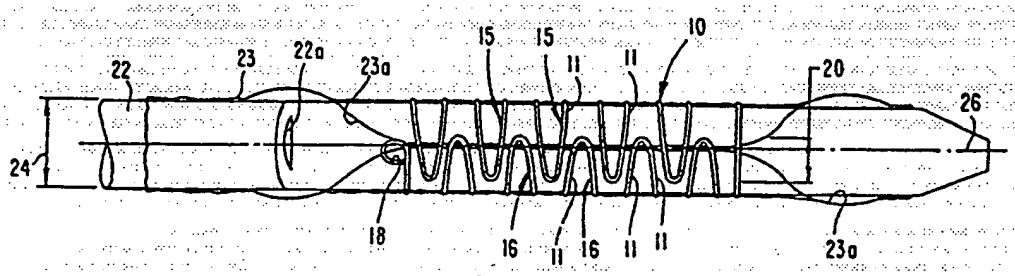


Fig.3

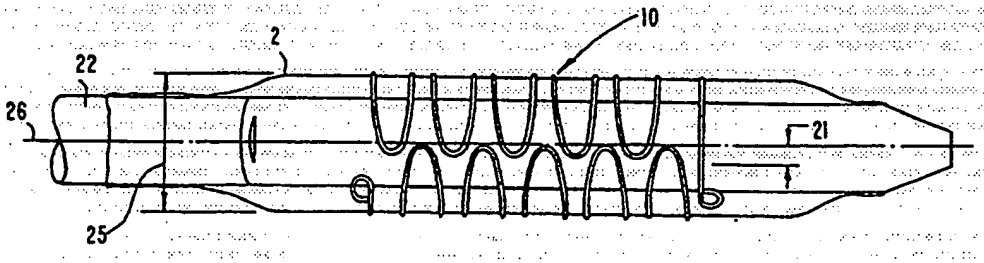
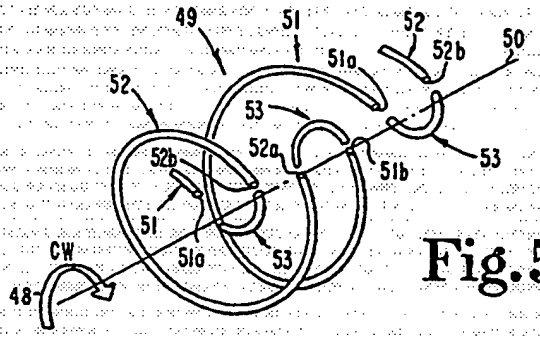


Fig.4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CW
48

Fig.5

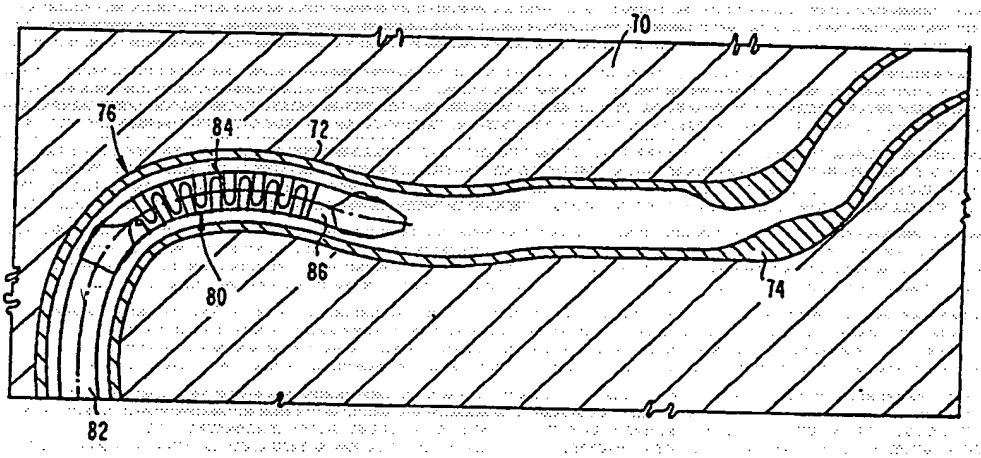
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Fig.6

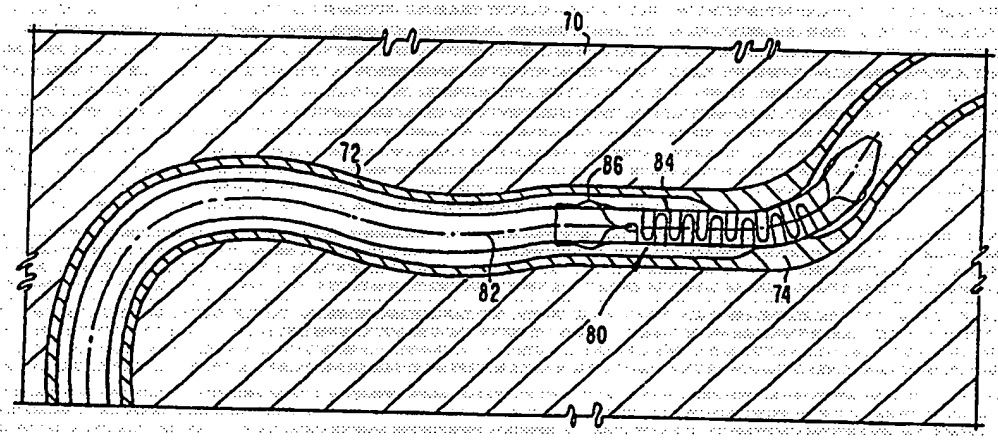

Fig.7

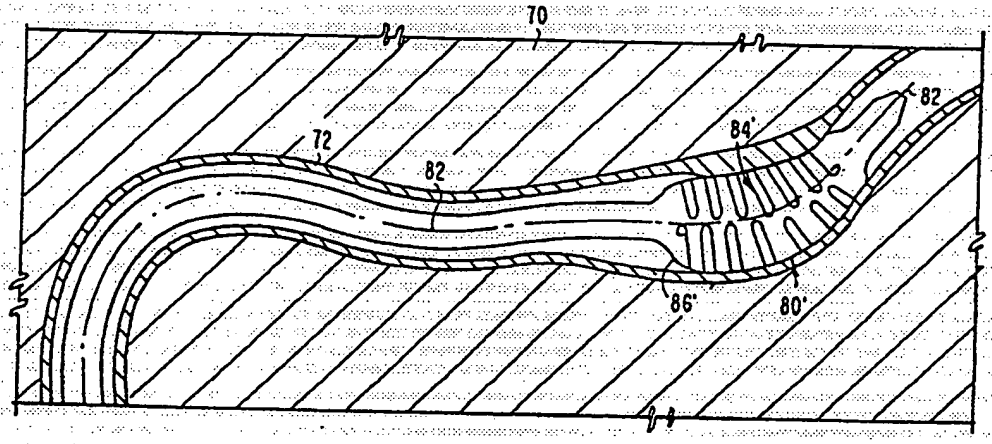

Fig.8

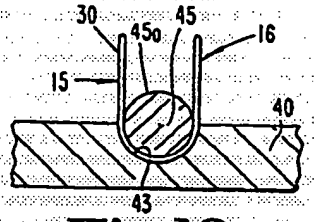

Fig.12

Fig.11

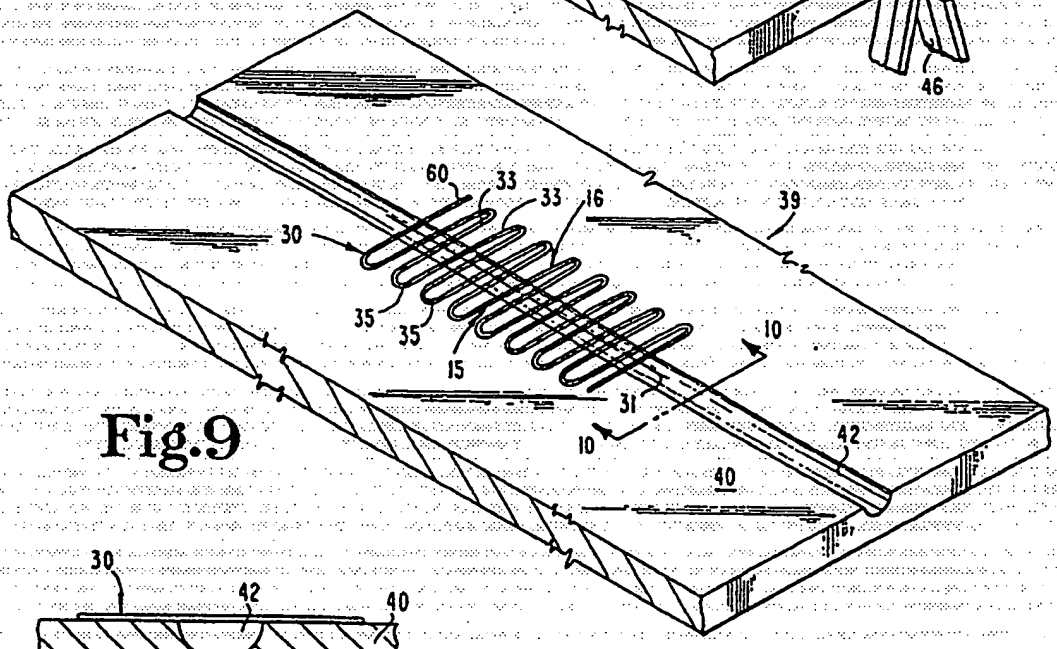

Fig.9

Fig.10

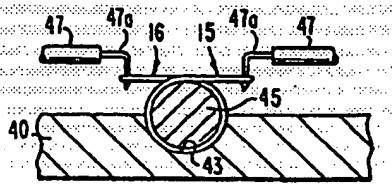

Fig.14

Fig.13

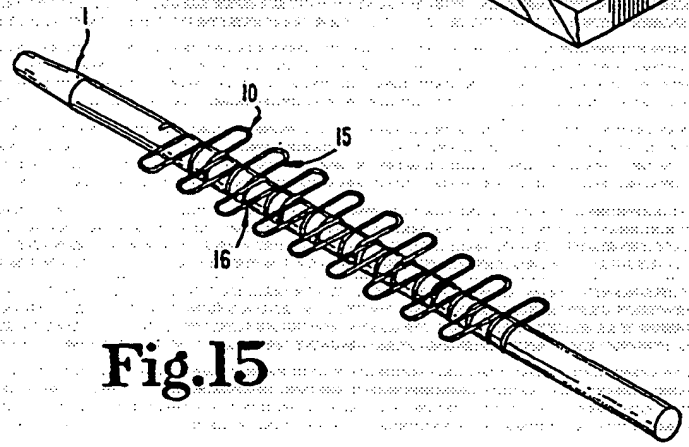

Fig.15